

Community Engagement Background

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I. Purpose and Design of this Module

The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) conducts research and develops reports and other materials for public distribution in order to advise the President of the United States on bioethical issues that arise as a consequence of advances in biomedicine and related areas of science and technology. To support ethics education and facilitate the integration of bioethical analysis into existing curricula across

traditional and non-traditional educational and professional settings, we have developed pedagogical materials designed to increase distribution of the Bioethics Commission's work and to facilitate easy access to the material in its reports by professors, instructors, teachers, and professional leaders (collectively "instructors").

This module was prepared for instructors who want to include in their teaching discussion of research-related community engagement. It provides foundational information, ethical reasoning, applications, questions, discussion points, and additional readings that are designed to give the instructor enough information to plan lectures, discussions, or activities. These materials are not intended to be a lecture script or outline, but rather to support the instructor in developing his or her own presentation(s).

In addition to the background information provided here, further modules provide a guide for instructors to facilitate incorporation of the Bioethics Commission's published reports as a resource for teaching and discussion. The featured Bioethics Commission reports illustrate relevant and current applications of community engagement.

Instructors are invited to use these materials, or any portion of them, to integrate bioethics into coursework and professional development activities in all disciplines. Feedback is welcome, including insight into how the materials have been used and suggestions for how they might be improved for use in the future. (Send feedback to education@bioethics.gov.)

II. Introduction

Community engagement is a mechanism—which can be approached in numerous ways—to involve members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research. Although research can move forward without participation from the community, ethical and practical reasons compel community input.

General ethical oversight of research involving human participants is provided by institutional review boards (IRBs), whose independent review and approval is required for such research to move forward. Engagement allows community members to articulate concerns or priorities, express reservations about the research, and identify vulnerable populations (groups in which the individuals are unable to protect fully their own interests) that might not be readily discerned by researchers. Such engagement can also identify potential implications or consequences of the research that might not yet be foreseen. Additionally, it allows the community as a group and individual potential research participants to consider more thoroughly the risks and benefits of participating in the research and to evaluate the designated protections in place for participants.

Involving community members from the early stages of research can also strengthen research design by accounting for local or unique variables that could affect the research and by shaping

the research question to more directly address the needs of the community. Community engagement helps to establish transparent, collaborative, and beneficial relationships between potential researchers and the communities with which they might work to conduct the research.¹ This is important, because beneficial relationships between researchers and communities can foster trust in scientific research and can lead to greater acceptance of scientific findings, for example beneficial interventions discovered in the research trials. These relationships could result in the identification of potential future research efforts that might further benefit the community.

III. Learning Objectives

Students should be able to:

1. Define community engagement and describe the different mechanisms of applying it as an approach to conducting research.
2. Describe the goals of community engagement.
3. Discuss the ethical basis for community engagement.
4. Identify and consider some of the challenges encountered in research-related community engagement.

IV. Background

A. What is Community Engagement?

Community engagement has been defined as “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people.”² This process results from a commitment on the part of both researchers and the community, and it requires an ongoing relationship among researchers, community members, and research participants throughout the course of the project, and in some cases after its completion. There are four critical elements of ethical and effective community-engaged research: location, time, commitment, and multiple

¹ UNAIDS/AVAC. (2011). *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials 2011, Second Edition*. Geneva: UNAIDS. Retrieved from http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf.

² Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. (NIH Publication No. 11-7782). Bethesda, MD: National Institutes of Health (NIH), p.7. Retrieved from <http://www.atsdr.cdc.gov/communityengagement/>.

viewpoints.³ Consideration of these elements, described in more detail in this module, helps to define the distribution of control, power, and trust in the research endeavor.

Community can be defined in a variety of ways. In the context of community-engaged research, the community with which investigators collaborate consists of the people that are either involved in or whose wellbeing is potentially affected by the proposed research, public health initiatives, policymaking, or other related activities.⁴ These groups might be affiliated based on geographical location, special interest, cultural identity, or other situations that connect them to the issue and community of concern. Key to successful community engagement is knowledge about how community members themselves define and experience their communities.⁵ In addition, “*the community*” can be dynamic and heterogeneous, and it is critical to account for diversity and change.

Examples of community engagement include, but are not limited to: conducting community-based participatory research (described in the following section of this module), seeking community input to define research priorities and design a study to address its needs, community monitoring of study progress, and using community advisory boards.⁶ An example of an active community advisory board is the Framingham Heart Study Ethics Advisory Board, which is part of a long-running epidemiological study funded by the National Institutes of Health that seeks to identify common factors contributing to heart disease by studying a large group of participants over an extended period of time.⁷ The Framingham Heart Study Ethics Advisory Board “enables participants and community members from the town of Framingham, Massachusetts, to advise researchers...on proposed research design and methods.”⁸

B. Types of Community Engagement

As an approach to research, community engagement can be practiced in numerous ways and to differing extents. Degrees of engagement cover a wide spectrum, and the level of engagement will depend on the type and complexity of the project.⁹ No single model of community

³ Isler, M.R., and G. Corbie-Smith. (2012). Practical steps to community engaged research: From inputs to outcomes. *Journal of Law, Medicine, and Ethics*, 40(4), 904-914.

⁴ Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. (NIH Publication No. 11-7782). Bethesda, MD: National Institutes of Health (NIH). Retrieved from <http://www.atsdr.cdc.gov/communityengagement/>.

⁵ MacQueen, K.M., et al. (2001). What is community? An evidence-based definition for participatory public health. *American Journal of Public Health*, 91(12), 1929-1943.

⁶ Presidential Commission for the Study of Bioethical Issues (PCSBI). (2011, December). *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC: PCSBI, p. 78.

⁷ Framingham Heart Study. (n.d.). About the Framingham Heart Study [Webpage]. Retrieved from <http://www.framinghamheartstudy.org/about/index.html>.

⁸ PCSBI. (2011, December), op cit, p. 78; For further information on the Framingham Heart Study Ethics Advisory Board, see Framingham Heart Study. (n.d.). Ethics Advisory Board [Webpage]. Retrieved from <http://www.framinghamheartstudy.org/about/ethics.html>.

⁹ Fleishman, A.R. (2007). Community engagement in urban health research. *Journal of Urban Health*, 84(4), 469-471.

engagement will work in all situations or in all kinds of research, and there is no consensus regarding the method of community engagement most appropriate for a given type of research.¹⁰ Engagement can be represented by the following spectrum:¹¹

1. Traditional Research

Traditional research methods mark the lowest end of the community engagement spectrum as, historically, research has been steered primarily by funding priorities and prior experimental data. Protocols are designed solely based on scientific method, ethical requirements, and feasibility; input from participants and the community generally is not sought. Recruitment of participants is typically based on scientific criteria specific to the protocol and researchers estimate how best to reach community members for recruitment purposes. Researchers generally are not connected to the community except through the research project. The researchers collect, analyze, and interpret data, report findings, and publish results on their own; community members typically have no part in the research beyond acting as participants in the protocol.

2. Community-Engaged Research

Community-engaged research spans the largest portion of the spectrum. In community-engaged research, the input of community members is sought to identify relevant issues for study, to create a culturally acceptable study design, or to identify and incorporate ethical considerations into study design and participant recruitment strategies. Establishing a community advisory board to consult with researchers is a common method that clearly values community input but stops short of establishing community representatives as full partners in the research endeavor. Whereas partners carry equal weight in research-related decision making, a community advisory board provides information and input, but does not have the authority to make final decisions. Community members might be involved in some level of data collection and analysis. Analysis, interpretation, and dissemination of results are shared explicitly with the community.

Along the spectrum of community-engaged research, the degree of engagement and cooperation between researchers and community members can be described as outreach, consulting, involvement, collaboration, and shared leadership, as shown in the following diagram:¹²

¹⁰ Ibid.

¹¹ Oregon Clinical and Translational Research Institute. (n.d.). Frequently Asked Questions about Community Engagement. Retrieved from http://www.ohsu.edu/xd/research/centers-institutes/octri/collaboration/upload/Frequently_Asked_Questions_about_Community-Engaged_Research.pdf.

¹² Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, op cit.

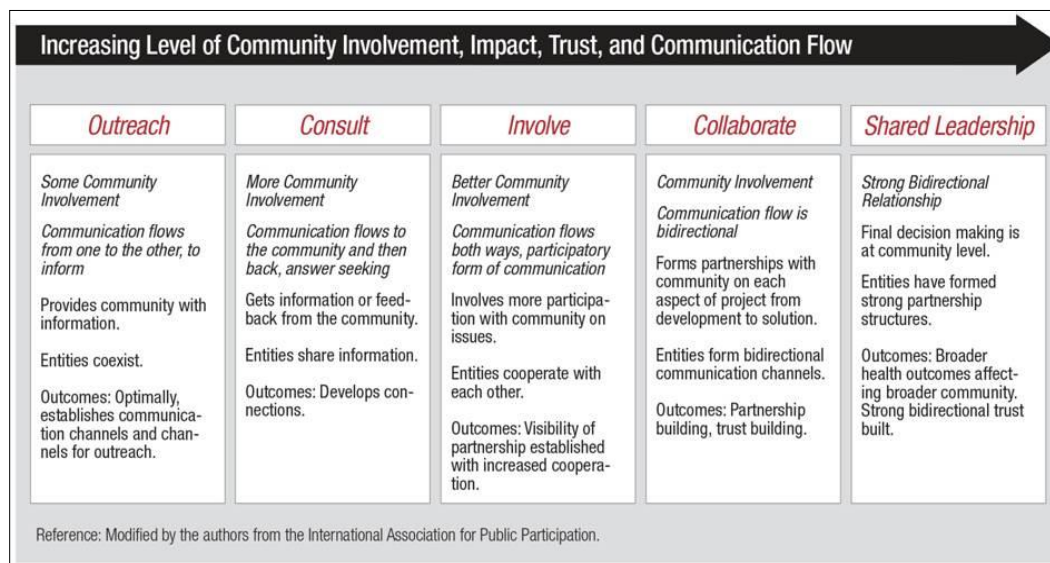


Figure 1: Continuum of Community Engagement Mechanisms.

Source: Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. (NIH Publication No. 11-7782). Bethesda, MD: National Institutes of Health (NIH), p.8. Retrieved from <http://www.atsdr.cdc.gov/communityengagement/>.

3. Shared Leadership Model

A shared leadership model, such as community-based participatory research, represents the maximum level of community participation in research, in which community members function as full partners in the project. In community-based participatory research, the community helps to identify the topic or issue to be studied based on its priorities, actively participates in forming the study design, and provides guidance to the researchers regarding participant recruitment and retention. Members of the community are involved in data collection, data are shared with the community, and community members typically work with researchers to analyze and interpret the data. Results are not only shared with the community, but community members also assist in disseminating results to the public. In addition, there is a strong emphasis on capacity building—the process of involving the local community in research with the goal of strengthening skills, competencies, and sometimes infrastructure to overcome existing social and/or economic barriers—within the community.

In community-based participatory research, explicit efforts typically are made to define the roles of community partners. For example, rather than creating a community advisory board, the

project might create a steering committee in which community members vote along with researchers on decisions regarding the project.¹³

C. Why Engage the Community in Research?

Many reasons have been enumerated for why researchers should engage communities in research, including facilitating open and ongoing communication with community members in order to build and maintain trust, adapting the research design to facilitate ethical implementation within specific communities, encouraging the uptake of positive research outcomes, and improving overall health outcomes in communities.¹⁴ While the impact of effective community engagement is the subject of ongoing study, indicators suggest that community input influences research agendas and study design, improves informed consent processes, increases public awareness and knowledge, increases acknowledgment of public contribution to research, enables individual participation in research, supports community organizations, and increases receptiveness of research among members of the public.¹⁵

Including community members in research-related decisions makes room for respectful discourse and encourages collective decision making. Engaging the community in the process of research serves multiple goals of both ethical and practical consequence. These goals include respecting communities, benefits to individuals and groups, increased legitimacy of research as perceived by the community, and a shared moral responsibility in the course of the research.¹⁶

1. Guiding Ethical Principles

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research authored *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1978, establishing standards for the ethical protection of participants in research based on three core principles: respect for persons, beneficence, and justice.¹⁷

Respect for persons is an ethical principle requiring that individuals are treated as independent and self-determining (autonomous) agents. This includes, for example, demonstrating respect

¹³ Isler, M.R., and G. Corbie-Smith, op cit.

¹⁴ Nuffield Council on Bioethics. (2005). *The Ethics of Research Related to Healthcare in Developing Countries: A Follow Up Discussion Paper*. London: Nuffield Council on Bioethics. Retrieved from http://www.nuffieldbioethics.org/sites/default/files/HRRDC_Follow-up_Discussion_Paper.pdf; Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, op cit.

¹⁵ Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, op cit.

¹⁶ Dickert, N., and J. Sugarman. (2005). Ethical goals of community consultation in research. *American Journal of Public Health*, 95(7), 1123-1127.

¹⁷ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1978). *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (DHEW Publication OS 78-0012). Washington, DC: Department of Health, Education, and Welfare. Retrieved from <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

through providing full information regarding research, employing a robust informed consent process, and respecting individuals' values and ways of life. Beneficence, and its corollary non-maleficence, entails an obligation on the part of researchers to undertake efforts to maximize possible benefits and minimize potential harms to research participants; this might apply to individual participants or to the community potentially affected by research. The principle of justice requires equitable distribution of the risks and benefits associated with research, which includes ensuring that the burden of research does not fall disproportionately to any groups within a community and, likewise, that potential benefits are distributed fairly among community members.

These core Belmont Report principles are “furthered by democratic deliberation, which the National Commission and subsequent commissions practiced in their work, and this Bioethics Commission explicitly [has added] as a critical principle for publicly accountable decision making.”¹⁸ “Democratic deliberation is a process that seeks to clarify and articulate factual and ethical issues at the core of a debate, to create consensus whenever possible, and to map the terrain of disagreements in a respectful way—when agreement is not immediately attainable—by encouraging reciprocity, respect for persons, transparency, publicity, and accountability.”¹⁹

It provides a means to engage moral disagreement democratically, which promotes the legitimacy of collective decisions, encourages public-spirited perspectives, promotes mutually respectful decision making, and facilitates the correction of mistakes made while undertaking collective actions.²⁰ In research, community engagement can serve as a component of a broader deliberation.

2. Respecting Communities

The principles of respect for persons, beneficence, and justice are the foundation upon which the Federal Policy for the Protection of Human Subjects, established by the U.S. Department of Health and Human Services (HHS) in 1991 and known as the Common Rule, was built. Eighteen federal agencies have adopted the Common Rule, codified by HHS in the Code of Federal Regulations as 45 C.F.R. Part 46.²¹

Community engagement demonstrates the ethical principle of respect and is important both on the individual and community levels. Respect for persons typically applies to the autonomy of individual research participants but can also be applied to the community as a whole. Since individuals are often deeply embedded in the cultures of their communities, research that breaches the principle of respect of an individual person can constitute an analogous lack of respect for the community as a whole. Similarly, respect for a community entails consideration

¹⁸ Presidential Commission for the Study of Bioethical Issues (PCSB). (2013, March). *Safeguarding Children: Pediatric Medical Countermeasure Research*. Washington, DC: PCSBI, p 23.

¹⁹ *Ibid*, p. 34.

²⁰ Gutmann, A., and D. Thompson. (1997). *Deliberating about bioethics*. *Hastings Center Report*, 27(3), 38-41.

²¹ *Protection of Human Subjects, HHS*. 45 C.F.R. Part 46.

of the diversity of perspectives of community members, such that community views are not oversimplified or homogenized.

One concern in human subjects research is exploitation, which sometimes can result from an inability of vulnerable groups and their members to exercise control over how their interests are represented and pursued. Engaging the community throughout the course of research does not eliminate every possibility of exploitation (in which individuals are not respected), but can help reduce exploitation through watchful and active participation.²² Community engagement can provide a vehicle of empowerment by creating the opportunity for marginalized voices to be heard.

Community members might participate at various points in the research process, including consulting in the development of protocols, designing the process for informed consent and information disclosure, identifying groups for recruitment, assisting in recruitment efforts, taking part in the conduct of research, and disseminating research results and findings.²³ These levels of involvement allow community members to identify potential harms that researchers might not otherwise recognize as outsiders to the community.

Risks that community members or representatives might identify can include both physical harm (to the individual) or a broader form of social, emotional, or psychological harm such as the risk of harm from stigmatization that could result from research outcomes or insensitive handling of results.²⁴ These risks can include risks to individuals through association with the community and risks to the community itself. Community engagement can help avoid or minimize these risks, for example, by supporting the design of a robust informed consent process that is tailored to the community, enhancing the ability of community members to understand fully the research and the implications of participation.

3. Securing Potential Benefits

It is important that researchers aim to secure access to potential benefits resulting from the research for participants and their communities (separate from any potential benefit that an individual might incur from study participation). When the community is involved in shaping research agendas in the planning stages, researchers have the opportunity to focus on issues of concern and potential benefit to the community rather than solely on the interest of the researcher or research sponsor, demonstrating beneficence toward the larger community.

²² Lavery, J.V., et al. (2010). Towards a framework for community engagement in global health research. *Trends in Parasitology*, 26(6), 279-283.

²³ Weijer, C., and E.J. Emanuel. (2000). Protecting communities in biomedical research. *Science*, 289(5482), 1142-1144.

²⁴ Anderson, E.E., et al. (2012). Research ethics education for community-engaged research: A review and research agenda. *Journal of Empirical Research on Human Research Ethics*, 7(2), 3-19; Isler, M.R., and G. Corbie-Smith, op cit.

Involvement of community members and representatives increases awareness and knowledge among the community both of the condition being studied and any research results that might ameliorate that health concern or situation. In addition to increased awareness, participation can engender trust between the community and researchers, increasing the likelihood that community members will be aware and take advantage of any benefits resulting from the research.²⁵

Community engagement can help ensure that the communities most likely to bear the burdens of research also have fair access to the benefits of research in accordance with the principle of justice. Engaging the community in planning protocols, recruitment, and distribution of research results provides the opportunity for the community to identify groups that might require particular consideration in order to prevent either overburdening them with research risk or omitting any group from the eventual distribution of the fruits of research.

4. Increased Legitimacy

When a community is engaged in a research project, there is a greater chance that researchers will develop and maintain its trust in the research and that the community will be more receptive to the research and potential benefit that results.²⁶ Despite these possibilities, perceived tensions can arise between the goals of community engagement and the notion of “good” science. Traditionally, scientists plan experiments and clinical trial strategies based solely on the scientific method and the best and most efficient way to generate valid data. In community-engaged research, the community might provide input into the protocols as well as research design. This involvement need not diminish the scientific validity of the protocol; rather it allows for multiple standards for success to be achieved and can increase the perceived legitimacy of the research from the community’s standpoint.

Researchers and the community must recognize the knowledge and values that each brings to the collaborative research endeavor. Researchers have scientific expertise and knowledge and value strong experimental protocol and scientific validity. Community members possess intimate knowledge of the community and its history and value the protection and strengthening of community culture, wellbeing, and health. Both sets of knowledge and values are equally important to the community engagement process and to ensuring that researchers and community members can converge on a common set of objectives for the research.

To alleviate tension between community input and decisions made by researchers to ensure scientific validity, researchers must clearly communicate the reasoning behind methodological decisions or risk inadvertently causing the community to question the integrity of researchers and their commitment to the community engagement and research processes.²⁷ Likewise, community

²⁵ Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, op cit.

²⁶ Nuffield Council on Bioethics, op cit.; Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, op cit.

²⁷ Anderson, E.E., et al., op cit.

members and representatives must effectively communicate their motivations and goals to the researchers.

5. Shared Moral Responsibility

Involving community members in the planning, recruitment, and implementation of research serves both to strengthen the ethical basis for decisions regarding how the research will proceed, and instill in the community partial moral responsibility for the investigation. Sharing in the moral responsibility for the research does not reduce the degree to which researchers are responsible for the research, rather it reinforces researchers' obligations to acknowledge and address community concerns.²⁸

The weight of shared responsibility in research can cause moral distress for some who are living or working in the community.²⁹ This distress can be ameliorated by empowered interaction with researchers and the ability to influence the course of research design and implementation, which requires a responsive relationship between community members and researchers. Failure of researchers to address the needs of the community could be perceived as a betrayal of trust.

D. Challenges in Community Engagement

The critical elements for ethical and effective community-engaged research—location, time, commitment, and multiple viewpoints—also present its greatest challenges. Additional resources are required, including hiring staff with relevant expertise, conducting research to inform the development of effective community engagement, and implementing engagement strategies. Research that includes community members as partners often moves outside of the physical location of the academic or private institution of the researchers, changing the way that researchers interact with the community. More time must be dedicated to developing a lasting relationship of mutual trust between researchers and the community. There must be a mutual commitment to the project and to community-oriented research. Finally, planning and conducting research must account for varying viewpoints on how to weigh the potential benefits, risks, and outcomes of the research. The degree to which these elements apply depends on the level of community engagement.

Another challenge is the potential for conflicts of interest. Community partners in research often function within their communities as care providers or leaders (e.g., health care providers, community organizers, teachers, public health officials). These dual roles can create competing obligations and confusion with regard to when they are providing services versus acting in their research capacity.³⁰ Such confusion can lead to “conflation of the obligations, risks and benefits of research participation with other clinical or social services,” inadvertently encouraging

²⁸ Dickert, N. and J. Sugarman, op cit.

²⁹ Anderson, E.E., et al., op cit.

³⁰ Ibid.

research participants to believe that research processes are more beneficial or less risky, which is sometimes referred to as “therapeutic misconception.”³¹

Additionally, community partners can experience conflicts of interest that can influence how they view portions of the research, for example, recruitment procedures if someone close to them is affected by the condition being studied.³² These concerns can be resolved in part by close and thorough attention to the informed consent process. Consistent clarification of the goals of the study and scope of participation are important to avoid coercion or undue influence in the recruitment process.³³

Similarly, researchers can experience conflicts of interests beyond the typically defined financial conflicts. For example, as research proceeds, poor or unexpected results can lead to truncation of the study or significant changes in study design. Having developed relationships with the community and its members, researchers can be conflicted about these developments and how they must proceed.

Respectful and ongoing dialogue between researchers and the community is particularly important in handling expectations and structuring the ways in which the community is involved. While researchers should accommodate benefits sought by the community through research participation when possible, it is important to note that “researchers cannot—and should not—accept uncritically everything that a community recommends or requests.”³⁴ Any community request or tradition that might “infringe upon human dignity, human rights, and fundamental freedoms” must not be upheld in the process of research.³⁵

E. Oversight for Community Engagement

Federal regulations require that federally supported research involving human participants be reviewed and approved by an IRB, unless it is considered exempt as defined in the regulations, which has the responsibility of verifying ethical treatment of participants and minimizing risk to participants.³⁶ Currently, there is no consensus regarding whether IRBs are the appropriate bodies to oversee community engagement initiatives. Although IRBs might review letters of support from community groups and partners with regard to a potential research project, they are not required to review or monitor the relationship between researchers and community or the degree of collaboration between them. As such, there is no formal oversight mechanism for

³¹ Isler, M.R., and G. Corbie-Smith, op cit.

³² Anderson, E.E. et al., op cit.

³³ Isler, M.R., and G. Corbie-Smith, op cit.

³⁴ The International Research Panel of the Presidential Commission for the Study of Bioethical Issues (PCSBI). (2011, September). *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues*. Washington, DC: PCSBI, p.8.

³⁵ United Nations Educational, Scientific and Cultural Organization. (2005). *Universal Declaration of Bioethics and Human Rights*. Paris: United Nations Educational, Scientific and Cultural Organization: Article 12.

³⁶ *Protection of Human Subjects, HHS*. 45 C.F.R. Part 46.

community engagement initiatives and researchers interested in developing community engagement strategies must seek out examples in the literature.

External review (by an IRB or similar mechanism) establishes independent evaluation of the consistency of research objectives and methods using an ethical framework. However, community engagement might entail evolving objectives and methods as community input and feedback is continuous, requiring a high degree of versatility that external review was not originally designed to accommodate. Researchers should be prepared to work closely with research protection officials to anticipate these unique features of community engagement.

V. Discussion Questions

The following questions are based on the information provided in the “Background” section above and are intended to reinforce important aspects of research-related community engagement. Important points are noted with each question to help the instructor guide a group discussion. The “Additional Resources” section will be helpful in answering these questions.

1. How does community engagement demonstrate the three central principles outlined in the *Belmont Report*?

Starting points for discussion:

- a. *Respect for persons*: Community engagement invites community members or representatives to voice their perspectives and opinions; it supports community member autonomy and addresses the unique situation and needs of the community based on their input.
- b. *Beneficence*: Community input helps researchers identify needs of the community and provides an opportunity to provide benefit to the community (separate from any potential direct benefit of participation in the study) by tailoring how the study is designed and conducted.
- c. *Justice*: Soliciting input from the community enables researchers to address just distribution of the burdens and potential benefits of research. Identifying vulnerable or disenfranchised groups within the community helps researchers ensure that the burdens of research are not disproportionately distributed to these groups and it also gives them information needed to ensure the equitable distribution of potential benefits.

2. How can community engagement be used as a component of democratic deliberation?

Starting points for discussion:

- a. ‘Democratic deliberation is a process that seeks to clarify and articulate factual and ethical issues at the core of a debate, to create consensus whenever possible, and to map the terrain of disagreements in a respectful way—when agreement is not immediately attainable—by encouraging reciprocity, respect for persons, transparency, publicity, and accountability.’³⁷
 - b. Community engagement can contribute as a component of a wider process of democratic deliberation; it encourages the inclusion of community members (individuals and their representatives) in meaningful and active participation in the ongoing public exchange of ideas.
- 3. Considering the challenges of community engagement, how might typical funding sources (i.e., research sponsors) need to adjust their expectations or requirements to encourage community engagement in research?**

Starting points for discussion:

- a. Funding sources might:
 - i. Acknowledge and demonstrate value for community engagement by requiring some form of community engagement in grant applications,
 - ii. Allow more time in the grant cycle or project timeframe to allow researchers to develop meaningful relationships with the community,
 - iii. Permit flexibility in research design (possibly by drafting more broad funding initiatives and requests for proposals) and create a process that allows for continued flexibility in some aspects of research design based on interaction with the community, or
 - iv. Allow for a wide range of mechanisms for reporting results, encouraging community participation.

VI. Exercises

Exercise A. *The UNAIDS/AVAC Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (GPP Guidelines) were designed to guide ethical relations between trial sponsors/implementers and their participating communities in executing HIV prevention trials. These guidelines identify core principles, essential issues, and minimum elements for how stakeholders should plan, conduct, and evaluate community engagement. The essential components of the GPP Guidelines can serve as a useful tool beyond HIV prevention studies and*

³⁷ Presidential Commission for the Study of Bioethical Issues (PCSB). (2013, March). *Safeguarding Children: Pediatric Medical Countermeasure Research*. Washington, DC: PCSBI, p. 34.

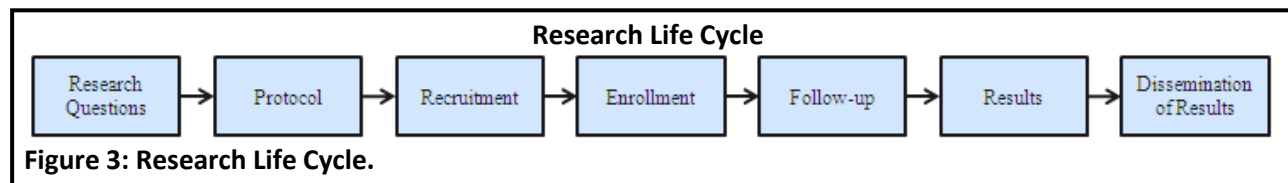
help emphasize key elements of community engagement generally. Drawing from the GPP Guidelines, answer the questions below.

UNAIDS/AVAC. (2011). *Good Participatory Practices: Guidelines for Biomedical HIV Prevention Trials 2011, Second Edition*. Geneva: UNAIDS.

Retrieved from

http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf.

- 1. Create an outline of effective community engagement for a hypothetical research project related to the subject matter of your class, research, or work. Include discussion about how to identify stakeholders, what mechanisms of engagement might be effective, and at what point(s) in the hypothetical project each engagement mechanism might occur.**
 - a. Based on your chosen research example, identify key stakeholders and the potential benefit that community engagement might provide to these groups: Who are the stakeholders? How might these stakeholders benefit from community engagement in the research?
 - b. Discuss mechanisms of community engagement: How can researchers demonstrate respect for community values; support understanding of research protocols, interpretations, and outcomes; maintain transparency throughout the research process; maintain accountability; and respect stakeholder autonomy in participation? Consider the following:
 - i. Stakeholder meetings
 - ii. Local informational and educational events
 - iii. Ongoing dialogue with community advisory committees or organizations
 - iv. Focus group discussions
 - v. Advisory groups
 - vi. Participant group discussions and informational sessions
 - vii. Meetings with pre-established community groups
 - c. What mechanisms of community engagement might be used to ethically and effectively complete each step of your project? For each step, when should community engagement occur?
- 2. Using as a guide the mechanism of community engagement for your sample project drafted in answering the previous question, discuss the Research Life Cycle (pictured below) and various ways in which researchers might engage stakeholders and community members.**



Adapted from: UNAIDS/AVAC. (2011). *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials 2011, Second Edition*. Geneva: UNAIDS, p. 35. Retrieved from http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf.

- a. At what point in the research life cycle should researchers implement various community engagement mechanisms that you outlined in the previous question?
- b. How might you modify your research protocol to incorporate Good Participatory Practice as it is described in *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials 2011, Second Edition*?

VII. Glossary of Terms

Beneficence: An obligation on the part of researchers to undertake efforts to maximize possible benefits and minimize potential harms to research participants.

Capacity building: Involving a local community in the research process with the goal of strengthening skills, competencies, and sometimes infrastructure to overcome existing social and/or economic barriers.

Common Rule: Current federal regulations that protect research participants, codified by the U.S. Department of Health and Human Services in the Code of Federal Regulations at 45 C.F.R. Part 46, Subpart A. Also known as “Human Subjects Regulations.”

Community advisory board: An advisory board consisting of community members that represent the interests of the community in advising and communicating with researchers or research sponsors.

Community-based participatory research: Research in which the community helps to identify the topic or issue to be studied based on local priorities, actively participates in developing the study design, and provides guidance to the researchers regarding participant recruitment and retention.

Community-engaged research: A mechanism to involve members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research.

Community engagement: The process of working collaboratively and engaging actively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people. [Adapted from *Principles of Community Engagement*, Second Edition (2011)].

Democratic deliberation: An approach to collective and collaborative decision making that seeks to clarify and articulate factual and ethical issues at the core of a debate, to create consensus whenever possible, and to map the terrain of disagreements in a respectful way—when agreement is not immediately attainable—by encouraging reciprocity, respect for persons, transparency, publicity, and accountability.

Distributive justice: An ethical principle that calls for equitable distribution of benefits and burdens across society—for example, the benefits and burdens of biomedical research, or of technological advances.

Exploitation: In human subjects research, the ability to take unfair advantage of participant vulnerability.

Institutional review board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of individuals recruited to participate in biomedical or behavioral research. The duties and responsibilities of IRBs are described in the federal regulations.

Respect for persons: Ethical principle requiring that individuals are treated as independent and self-determining (autonomous) agents and that persons with diminished autonomy are entitled to additional protections.

Vulnerable populations: Groups of individuals who are potentially unable to exercise control over how their interests are represented and pursued.

VIII. Additional Resources

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